REMARKS

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

I. CLAIM STATUS & AMENDMENTS

Claims 1-3 and 5 are pending in this application.

Claims 1 and 2 were rejected, and claims 3 and 5 were objected to.

Claims 1 and 3 have been amended.

Support for the "which is a signal transduction molecule for cell proliferation" added to claim 1 can be found in the specification, for example, at page 1, lines 11-12 and page 4, lines 21-22.

Claim 3 has been rewritten in independent form. Support for this amendment can be found in original claims 1 and 3.

Therefore, no new matter has been added by this amendment.

II. REJECTION UNDER 35 U.S.C. § 102

Claims 1 and 2 were rejected under 35 U.S.C. § 102(b), as anticipated by Yu et al., Genome Research, Vol. 7, No. 4, pp. 353-358 (1997). See pages 2-3 of the Office Action.

This rejection is respectfully traversed as applied to the amended claims for the following reasons.

To anticipate a claim, a cited prior art reference must either expressly or inherently teach each and every element of the claimed invention. See M.P.E.P. § 2131.01.

The claims call for an isolated human protein hAMSH, which is a signal transduction molecule for cell proliferation, and has the amino acid sequence of SEQ ID No. 1.

Yu fails to disclose or suggest an **hAMSH protein**, let alone one having the **amino acid sequence of SEQ ID No. 1**. In fact, Yu fails to disclose an amino acid sequence. Instead, Yu discloses a **nucleic acid**, and not a protein. Also, Yu fails to disclose the **function** of the protein as a signal transduction molecule for cell proliferation. For these reasons, Yu cannot anticipate the claimed protein.

On page 2 of the Office Action, it is stated that "Yu et al. teach a nucleic acid sequence, GenBank Accession No. AF052135, that encodes a protein which is 100% identical to SEQ ID No: 1." In the sentence bridging pages 2-3, it is indicated that "[t]he amino acid sequence of SEQ ID No: 1 is an inherent feature of AF052135 because one skill in the art would be in possession of the sequence and be able to envision it once he or she had possession of the nucleic acid sequence." Thus, it appears that the Office's relies on inherency argument.

To have inherent anticipation, the missing descriptive material must be "necessarily present" in the disclosed prior art product. Also, under the doctrine of inherency, it is well established that where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. See M.P.E.P. § 2112.01, Sections I-II.

In the instant case, the claimed protein and the alleged disclosed nucleic acid are **not** the same nor are they substantially identical products. In fact, it is well established that proteins and nucleic acids are distinct and entirely **different chemical compounds** with vastly different structures and functions. This fact is evident by the different classifications for each by the USPTO, and the current restriction practice at the USPTO, wherein both are treated as separate and distinct inventions. Thus, it is clear that they are entirely **different products**, and as such, inherency is not applicable.

Furthermore, it is respectfully submitted that a protein and a nucleic acid do not anticipate nor render each other obvious. The established relationship between a nucleic acid and the protein it encodes in the genetic code does not render a gene *prima facie* obvious over its corresponding protein (or vice versus) in the same way that closely related structures in chemistry may create a *prima facie* case. See In re Bell, 991 F.2d 781, 26 USPQ2d 1529 (Fed. Cir. 1993); In re Deuel, 51 F.3d 1552, 1558-59, 34 USPQ2d 1210, 1215 (Fed. Cir. 1995). Again, a gene and a protein are not closely related structures.

As to the nucleic acids disclosed in Yu, kindly note that Yu describes 65 cDNA clones in Table 1, which are submitted to the GenBank data library under Accession Nos. **U79240-U79304**. See the last paragraph of Abstract. Contrary to the assertion in the Office Action, it does not appear

that Accession No. **AF052135** is described in the Yu reference. In this regard, it is not included in the 65 cDNA clones on Table 1. Thus, it is not evident that Yu discloses Accession No. AF052135.

Also, as to Accession No. AF052135 (a copy of which is attached herewith), it is respectfully noted that this entry, similar to Yu, does **not** disclose or suggest the **amino acid sequence** of the claimed invention. Nor does it disclose or suggest the **function of the protein**, *i.e.*, as a signal transduction molecule for cell proliferation.

In this regard, neither Yu or Accession No. AF052135 can be said to disclose or suggest each and every element of the claimed invention, namely, the an hAMSH protein, the amino acid sequence of SEQ ID No. 1 and the function of the claimed protein. Thus, they cannot anticipate the claimed protein.

Furthermore, Yu and Accession No. AF052135 are not enabling for the claimed hAMSH protein. It is well established that to anticipate, the prior art reference must also be enabling. That is, the reference must place the allegedly disclosed subject in the possession of the public. As stated above, a disclosure of a nucleic acid does not place the public in possession of a functional protein with a specific amino acid sequence, nor does it suggest the function of the protein. Again, Yu and Accession No. AF052135 disclose a nucleic acid sequence, and not a protein. They mention nothing regarding the specific amino acid sequence of the protein nor the function of the protein.

In sum, Yu in view of Accession No. AF052135 fail to disclose or suggest each and every element of the claimed invention, and the references are non-enabled for the claimed protein.

Therefore, the rejection of claims 1 and 2 under 35 U.S.C. § 102(b) is untenable and should be withdrawn.

III. CLAIM OBJECTIONS & ALLOWABLE SUBJECT MATTER

Claims 3 and 5 were object to as dependent upon a rejected base claim, but would be allowable if rewritten in independent form including the limitations of the base claim. See page 3.

Applicants acknowledge with thanks the Examiner's indication that claims 3 and 5 would be allowable if rewritten in independent form. Claim 3 has been amended as suggested by the

Examiner to be in independent form. Claim 5 depends on claim 3. Thus, it is respectfully submitted that claims 3 and 5 are now allowable.

CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and early notice to that effect is hereby requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

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Facsimile: 202-721-8250
February 28, 2005

ATTACHMENT TO AMENDMENT AND REPLY:

1. A copy of the GenBank Accession No. AF052135 (2 pp.).

BEST AVAILABLE COPY

1: AF052135. Reports **Homo sapiens clon...[gi:3360444]** Links

```
LOCUS       AF052135                1462 bp    mRNA    linear   PRI 05 AUG-1998
DEFINITION  Homo sapiens clone 23625 mRNA sequence.
ACCESSION   AF052135
VERSION     AF052135.1  GI:3360444
KEYWORDS    FLI_CDNA.
SOURCE      Homo sapiens (human)
  ORGANISM  Homo sapiens
            Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
            Mammalia; Eutheria; Euarchontoglires; Primates; Catarrhini;
            Hominidae; Homo.
REFERENCE   1  (bases 1 to 1462)
  AUTHORS   Andersson,B., Wentland,M.A., Ricafrente,J.Y., Liu,W. and Gibbs,R.A.
  TITLE     A 'double adaptor' method for improved shotgun library construction
  JOURNAL   Anal. Biochem. 236 (1), 107-113 (1996)
  MEDLINE   96207227
   PUBMED   8619474
REFERENCE   2  (bases 1 to 1462)
  AUTHORS   Yu,W., Andersson,B., Worley,K.C., Muzny,D.M., Ding,Y., Liu,W.,
            Ricafrente,J.Y., Wentland,M.A., Lennon,G. and Gibbs,R.A.
  TITLE     Large-scale concatenation cDNA sequencing
  JOURNAL   Genome Res. 7 (4), 353-358 (1997)
  MEDLINE   97264341
   PUBMED   9110174
REFERENCE   3  (bases 1 to 1462)
  AUTHORS   Yu,W., Sarginson,J. and Gibbs,R.A.
  TITLE     Direct Submission
  JOURNAL   Submitted (05-MAR-1998) Molecular and Human Genetics, Baylor
            College of Medicine, One Baylor Plaza S930, Houston, TX 77030, USA
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      481 atgaagaaaa gaagaaggaa gcagaggaat tggcccggaa catggccatc cagcaagagc
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